

### **DETAILED ACTION**

Due to the complex nature of the claims, no request for oral election is being made.

Please see MPEP 812.01.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

### **Lack of Unity – Three Groups of Claims**

Group I, claim(s) 13-17, drawn to a method of treating cancer in a mammal, comprising administering to the mammal a compound of formula I.

Group II, claim(s) 18-22, drawn to a pharmaceutical composition comprising a compound of formula I or formula II.

Group III, claims 23-24, drawn to a pharmaceutical combination comprising formula I and a compound of formula II.

Groups I-III do not related to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: administration of a pyrimidine and quinazoline is not novel (See US Patent 4,510,311 to Eckstein, claim 1). Therefore, a holding of lack of unity amongst the inventions of Group I-III is proper.

### **Election**

This application contains claims directed to more than one species of the generic invention. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, applicant is required to elect one compound (see instant claims 13-24). If applicant elects a specie from the above specie election which is not found in the instant disclosure as filed, specie election may be considered new matter.

Applicant is advised that a reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement is traversed (37 CFR 11.43) and (ii) identification of claims encompassing the elected invention.

The election of an invention or species may be with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election with traverse.

Should applicant traverse on the grounds that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

#### **Election/Restrictions Proper**

MPEP 809.02(d) states “[w]here only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such multiplicity of species

that an unduly extensive and burdensome search is necessary." Here, the claims recite such a multiplicity of species that an unduly extensive and burdensome search would be necessary if all of the claimed species were to be examined simultaneously.

The inventions above are patentably distinct. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement and double patenting issues. Burden also resides in the examination of independent claim sets for clarity, enablement and double patenting issues. Further, a references that would anticipate the invention of one group would not necessarily anticipate or even make obvious the other group. Finally, the consideration for patentability is different in each case. Thus, it would be undue burden to examine all of the above inventions in one application and the restriction for examination purposes as indicated above is deemed proper.

#### **Notice of Possible Rejoinder**

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for the process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoinder process claims will be withdrawn, and the rejoinder process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all the criteria for patentability including the requirements of 35 U.S.C 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims not commensurate in scope with allowable product will not be rejoined. See MPEP 841.06(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01

#### **Inventorship Notice**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Pagonakis whose telephone number is 571-270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Ardin Marschel/  
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